ENVIRONMENTAL TESTING LABORATORY CERTIFICATION BULLETIN

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PT Corrective Action

Failed PT studies for an analyte [field of proficiency testing] will occur even if just based on the statistical probability of things. Most often the investigation will find something out of the ordinary that can be fixed. These small fixes brought on by consistently challenging the process increase the quality of the product incrementally over time.

The ELCP has required the labs to submit their corrective action for many years. During the NELAC standards phase in and proficiency testing switch over to private providers, many labs got out of the habit. The ELCP is tracking failed PT results against corrective action documentation received.

The NELAC standard at **2.7.4 Failed Studies and Corrective Action** is written as follows: *Whenever a laboratory fails a study, it shall determine the cause for the failure and take any necessary corrective action. It shall then document in its own records and provide to the Primary Accrediting Authority both the investigation and the action taken.*

Occasionally a laboratory may know that results they are capable of producing at the time are not to the level of quality they would want to report. The laboratory may delay testing client samples until the problem is corrected. If a PT study falls into this time, the lab may miss the reporting date of the study while waiting for the problem to be corrected. In this situation, the laboratory may let The ELCP and the PT provider know they are withdrawing from the study. Not reporting the study will then not be held against the laboratory's certification. Remember that the laboratory must still meet the requirement of performing two studies each year not over 7 months apart.

The NELAC standard at **2.7.7 Withdrawal from PT Studies** is written as follows: *A laboratory may withdraw from a PT study for an analyte(s) or for the entire study if the laboratory notifies both the PT Provider and the Primary Accrediting Authority before the closing date of the PT study.* This does not exempt the laboratory from participating in the semiannual schedule.

What is approximately six months?

The NELAC standard at **2.7.2 Initial or Continuing PT Studies** is written as follows: *A laboratory seeking to obtain or maintain accreditation shall successfully complete two initial or continuing PT studies for each requested field of proficiency testing within the most recent three rounds attempted. For a laboratory seeking to obtain accreditation, the most recent three rounds attempted shall have occurred within 18 months of the laboratory's application date. Successful performance is described in Appendix C. When a laboratory has been granted accreditation status, it shall continue to complete PT studies for each field of proficiency testing and maintain a history of at least two acceptable PT studies for each field of proficiency testing out of the most recent three. For initial accreditation, the laboratory must successfully analyze two sets of PT studies, the analyses to be performed at least 15 calendar days apart from the closing date of one study to the shipment date of another study for the same field of proficiency testing. For continuing accreditation, completion dates of successive proficiency rounds for a given field of proficiency testing shall be approximately six months apart. Failure to meet the semiannual schedule is regarded as a failed study. Initial or continuing PT Studies must meet all applicable criteria described in this chapter and associated appendices.*

This section of the standard has a great deal of information. Probably the least straightforward part of it is the reference to keeping PT studies in the suggested time frames, specifically approximately six months apart. To make this an auditable time period the ELCP has adopted an interpretation that approximately six months

means no more than 7 months from the closing date of one study to the closing date of the subsequent study.

Now, with all of that said the requirement for the level of participation found in the NELAC Standard at **2.4.1 Required Level of Participation** requires that: *Each laboratory shall participate in at least two PT studies for each field of proficiency testing per year….*

It is important to remember that PT is evaluated by analyte [field of proficiency testing] which means studies for each analyte must be no more than 7 months apart [closing date to closing date]. Make up studies, done as soon as 15 days after the closing date of the previous study, "start the clock" for the analytes in the makeup study. In essence you can do a study every 15 days but they must be done at least two times each year and within 7 months of the last closing date.

When PT studies do not meet these criteria [at least two times each year and within 7 months] it counts as if the study was not done and all analytes fail. This failure is counted into the "two of three" grading structure and can have dire consequences on a laboratories certification status for the effected analytes.

Radiochemistry Proficiency Testing

Studies are now available from NELAC approved PT providers

There are currently only limited PT materials available and even then not all analytes [fields of proficiency testing] are covered in the approved PT studies. For any analyte available from an approved PT provider, that analyte must have successful PT performance to continue certification for the analyte. As an interim step, laboratories are encouraged to use some form of PT from any source [since there are no approved providers for some analytes] to evaluate their radiochemistry analytes where PT is not available. This PT used to cover analytes without approved PT should be treated as formal PT challenges with the corrective action taken for failures and keeping the frequency the same as for other approved PT programs used for certification.

Remember that even though there is limited availability of approved analytes participation is required when PT for an analyte is available from and approved PT provider. It is required!!!!

As more PT providers are approved and analytes are made available in approved studies, the PT requirement becomes official and continued certification will hinge on successful PT participation. The NELAC website (**http://www.epa.gov/ttn/nelac**) provides information to obtain the current listings of accredited proficiency test providers in both electronic and print formats. The listing includes provider contact information and fields of testing offered. For example, the NELAC site provides a link to the NIST website http://ts.nist.gov/nvlap (then go to Chemical Calibration and Providers of Proficiency Testing) listing of NVLAP accredited providers. The NELAC site also provides contact information needed to obtain a printed copy of this information from NIST NVLAP.

RCRA proficiency testing [PT]

The scope of certification is currently done by program then method and analyte. The future of the NELAP standards seems to be pushing toward an certification by matrix then method and analyte. This will not make a significant difference in the way the ELCP does things since the matrix for fields of certification uses matrices that nearly match the programs currently being used.

The definition of **Matrix** is actually written as**:** the substrate of a test sample.
Field of Accreditation Matrix: these matrix definitions shall be used when accrediting a laboratory (see Field of Accreditation).
Drinking Water: any aqueous sample that has been designated a potable or potential potable water source.
Non-Potable Water: any aqueous sample excluded from the definition of Drinking Water matrix. Includes surface water, groundwater, effluents, water treatment chemicals, and TCLP or other extracts.
Solid and Chemical Materials: includes soils, sediments, sludges, products and by-products of an industrial process that results in a matrix not previously defined.
Biological Tissue: any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.

Other more specific matrices are used elsewhere in the standards to define quality system requirements for the purpose of batch and QC requirements.

The disconnect comes with the PT materials available through approved providers. There are

currently no PT materials available in solid form. As an interim step, laboratories are encouraged to use some form of PT from any source [since there are no approved providers] to evaluate their solid methods. This PT should be treated as a formal PT challenges with the corrective action taken for failures and keeping the frequency the same as for other approved PT programs used for certification. Laboratories who analyze samples for ground water only using RCRA methods should analyze a PT sample from a CWA-Water NELAC PT approved provider.

When RCRA PT providers are officially approved the PT requirement becomes official and continued certification will hinge on successful PT participation. The NELAC website (**http://www.epa.gov/ttn/nelac**) provides information to obtain the current listings of accredited proficiency test providers in both electronic and print formats. The listing includes provider contact information and fields of testing offered. For example, the NELAC site provides a link to the NIST website (http://ts.nist.gov/nvlap then go to Chemical Calibration and Providers of Proficiency Testing) listing of NVLAP accredited providers. The NELAC site also provides contact information needed to obtain a printed copy of this information from
NIST NVLAP.

How a Certified Laboratory Adds a Method or Analytes

The process to add to an existing certification takes one of several paths depending on how the certification is granted.

For laboratories that have certification based on an onsite assessment by the ELCP, and request a new method they must provide: the current method SOP, a completed method based measurement systems tool, all PT for the last 12 months and detection limit study summaries for each analyte. Depending on the technology of the method and the laboratory's certification for similar technology, an onsite assessment may be necessary

For laboratories that have certification based on recognition through NELAP accreditation, and request a new method offered for accreditation by their Primary Accreditation Authority, they must provide: have their primary accrediting authority add the method and analyte or analytes to the laboratory's accreditation list and supply a copy to ELCP.

For laboratories that have certification based on an onsite assessment by the ELCP, and request an additional analyte for an existing method, they must provide: all PT for the last 12 months and detection limit study summaries for each analyte.

For laboratories that have certification based on recognition through NELAP accreditation, and request a new method not offered for accreditation by their Primary Accreditation Authority, they must provide: the current method SOP, a completed method based measurement systems tool, all PT for the last 12 months and detection limit study summaries for each analyte. Depending on the technology of the method and the laboratory's certification for similar technology, an onsite assessment may be necessary.

For laboratories that have certification based on recognition through NELAP accreditation, and request an analyte [in an accredited method] not offered for accreditation by their Primary Accreditation Authority, they must provide: all PT for the last 12 months and detection limit study summaries for each analyte.

The Environmental Testing Laboratory Certification Bulletin is published periodically by the Utah Department of Health, Division of Epidemiology and Laboratory Services, Bureau of Laboratory Improvement, to disseminate regulatory and general information to Utah certified laboratories.

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